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Patentanmeldung Nr. Patent application No. Demande de brevet n°

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Der Präsident des Europäischen Patentamts;
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
p.o.

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Bezeichnung der Erfindung/Title of the invention/Titre de l'invention:
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Compositions and methods for promoting lipid assimilation in pets

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SPECIFICATION

Title

COMPOSITIONS AND METHODS FOR PROMOTING LIPID ASSIMILATION IN PETS

Field of Invention

This invention relates generally to a food and/or food supplement product for pets and to its use in improving lipid absorption. In particular, it relates to improving lipid absorption in senior cats suffering the effects of pathologies and/or aging. The invention extends to methods of enhancing lipid digestibility and/ or assimilation in pet animals.

Background to the Invention

Studies on senior cat nutrition have shown that a significant number of older pets – such as those above the age of 9 years - exhibit a decreased capacity to digest fat. Several scientific publications have likewise reported an age-related decrease in lipid digestibility in cats (Burkholder, WJ. Age-related changes to nutritional requirements and digestive function in adult dogs and cats. JAVMA, Vol 215, No. 5, September 1, 1999; Nicholson A, Watson ADJ, Mercer JR. Fat malassimilation in three cats. Australian Veterinary Journal, Vol. 66, No. 4, April, 1989; Peachey SE, Dawson JM, Harper EJ. The effects of aging on nutrient digestibility by cats fed beef tallow, sunflower oil or olive oil enriched diets).

There can be any of a number of pathologies that can lead to poor digestibility of lipids. Malabsorption and maldigestion can occur from almost any diffuse disease of the intestine, from exocrine pancreatic insufficiency or from unknown causes. In the case of cats, pancreatitis occurs at a prevalence rate of about 0.15% to 3.5% and may account for some cases of poor fat digestibility. Diffuse intestinal diseases, such as intestinal lymphoma, small intestinal bacterial overgrowth, inflammatory bowel disease and liver disease, may also lead to reduced nutrient absorption in the small intestine.

Cases of pancreatic insufficiency are sometimes treated in veterinary practice by the addition of raw pancreas to the diet of the animal. The pancreas should not be heated to avoid denaturation of digestive enzymes. This kind of procedure is not convenient for the

"Digestibility", as used in this specification, means the quantity, expressed in percentage form, of a nutrient that is digested and absorbed in relation to the total nutrient quantity ingested by the animal.

"Assimilation", as used in this specification, means the process of incorporation of simple molecules, produced from food digestion and absorbed into the body, into the complex compounds forming the constituents of the organism.

It is thus an object of the invention to provide a nutritional product that, when administered to a pet displaying low lipid digestibility, improves the digestibility of lipid and lipid-linked compounds. Another object is to provide the pet and pet owner with advantages associated with effective lipid absorption.

A further object is to provide a complete pet food or supplement for a complete pet food that aids the pet to absorb lipid and lipid soluble nutrients in its diets.

Another object of the invention is to provide a method of improving lipid absorption in a pet animal, especially a senior pet.

A further object is to provide a means of improving the transportation of fat-soluble vitamins and essential fatty acids into the a pet's tissues.

Summary of Invention

The invention provides compositions and products that include them, for providing benefits related to the effective assimilation of a lipid or a lipid fraction. It also provides methods of improving or maintaining the capacity of a pet animal to assimilate a lipid or a lipid fraction effectively and to enable it to derive a benefit therefrom.

Therefore, according to the invention, a method of providing a pet with a benefit relating to effective assimilation of a lipid or lipid fraction comprises the steps of administering to the pet, as a part of, or in addition to, its regular diet, an edible composition that contains an ingredient that maintains, promotes or enhances the capacity of the pet to digest lipid efficiently.

- Outward appearance
- The pet-to-owner relationship
- Aging; or
- General health aspects.

Where the benefit is related to gut function, it may be observed in any one or more of:

- Increased nutrient and energy digestibility;
- Improved gut microflora, such as is observed in decreased small intestine bacterial overgrowth;
- Improved fecal consistency and/or odor;
- Optimized fecal volume;
- Improved regularity of food transit time;
- Reduced flatulence;
- Enhanced gut detoxification; and
- Improved absorption of fat-soluble nutrients.

The fat-soluble nutrients are preferably fatty acids, certain antioxidants and vitamins A, D, E and K.

Where the benefit is related to outward appearance, it may be observed in any one or more of:

- Improved body condition;
- Improved muscle tone;
- Improved skin and coat condition; and
- A younger look.

Where the benefit is related to owner relationship it may be observed in any one or more of:

- Increased levels of physical activity;
- Improved pet-owner interaction;
- Improved pet-owner bonding;
- Increased playfulness; and
- Improved alertness, mental performance and / or cognitive ability.

Where the benefit is related to aging, it may be observed in any one or more of:

- Delayed onset of signs of aging;

In an embodiment of the invention, the pancreas extracts comprise lipase derived from a non-pancreatic source. In an embodiment, the non-pancreatic source is a fungus.

According to another aspect of the invention, an edible composition for use in maintaining, improving, promoting or otherwise enhancing lipid digestibility in a pet animal comprises a lipid assimilation-promoting ingredient for administering regularly, according to predetermined directions, to a pet animal.

In an embodiment, the composition is prepared in an industrial process and packaged as a ready-to-eat meal.

In an embodiment, the lipid assimilation-promoting ingredient is provided in a container for addition to a separately packaged complete meal or for administering apart from a meal. In an embodiment, the ingredient is provided in a pharmaceutically acceptable carrier.

In an embodiment, the ingredient is selected from the group consisting of pancreatic function promoters, liver function-promoters, intestinal mucosa function promoters and combinations thereof.

In a further aspect of the invention, a method of improving the capacity of a pet animal to absorb an essential nutrient comprises the step of improving the capacity of the animal to absorb a lipid or lipid fraction that is a carrier of the essential nutrient. Preferred essential nutrients include vitamin E and arachadonic acid (or ARA).

The invention extends, in another aspect, to the use of a lipid digestibility-enhancing agent in the manufacture of a dietary composition or dietary supplement, for the provision of a benefit relating to optimal lipid absorption in a pet animal. The benefit may be any one of those listed above.

According to another aspect of the invention, a method of improving the appearance of a pet comprises the step of increasing its capability to digest fat in its diet wherein fat digestion capability is increased by feeding the pet a diet that contains an agent selected from:

- a fat emulsifier / emulsification system

Another advantage is that it provides an improvement of their nutritional status. Through this, there are further benefits expected, such as improvement in the quality of life and extended longevity of the pet and greater satisfaction of the owner.

A still further advantage of the invention is that it may be applied not only to clinically healthy senior pet cats, but also to cats with Exocrine Pancreatic Insufficiency (EPI) and a wider range of digestive deficiencies that contribute to lipid malabsorption, for which the mechanisms are not yet fully understood.

Brief Description of Accompanying Drawings

Figure 1 is a graph tracking the relationship between lipid digestibility and serum vitamin E level in pet cats.

Detailed description of embodiments

It has been found that in pet animals, the absorption of lipid is highly correlated with the absorption of other essential nutrients, for example vitamin E. Hence, a pet with low lipid digestibility is susceptible to deficient or sub-optimal nutritional status, which can compromise its health.

This invention seeks to provide means of prevention and relief for pets that are susceptible to develop, or that have already developed, reduced lipid absorption capability from any cause. Such a cause may include EPI, inflammatory liver disease, pancreatitis, inflammatory bowel disease, intestinal lymphoma, and idiopathic (unknown cause) malabsorption. The invention provides a means for increasing lipid absorption through nutrition management. Such management can be carried out by the pet owner, care giver or keeper. By implementing it as a regimen that maintains, improves, promotes or otherwise enhances lipid digestibility, various health and wellness benefits can ensue. These are set out more fully below.

Thus, a nutrition management regimen for maintaining, improving, promoting or otherwise enhancing lipid digestibility in a pet animal, comprises a lipid absorption-promoting ingredient for feeding regularly to the pet animal in need thereof, according to

Where the pancreatic function promoter is a pancreatic extract, the extract preferably includes pancreatic lipase. However, lipase derived from a non-pancreatic source may, in addition or alternatively, be used.

In preferred embodiments of the invention, the gut pH-modifying agent is a prebiotic or a probiotic micro-organism, or a combination thereof. The prebiotic may be obtained from any suitable natural or purified source, for example chicory, and may comprise inulin or an oligosaccharide. Should a probiotic microorganism be selected, it needs to be one that, via fermentation processes in the gut, regulates the gut pH. In general, probiotic microorganisms produce organic acids such as lactic acid and acetic acid which inhibit the growth of pathogenic bacteria such as *Clostridium perfringens* and *Helicobacter pylori*. Examples of suitable probiotic micro-organisms include yeasts such as *Saccharomyces*, *Debaromyces*, *Candida*, *Pichia* and *Torulopsis*, molds such as *Aspergillus*, *Rhizopus*, *Mucor*, and *Penicillium* and *Torulopsis* and bacteria such as the genera *Bifidobacterium*, *Bacteroides*, *Fusobacterium*, *Melissococcus*, *Propionibacterium*, *Enterococcus*, *Lactococcus*, *Staphylococcus*, *Peptostreptococcus*, *Bacillus*, *Pediococcus*, *Micrococcus*, *Leuconostoc*, *Weissella*, *Aerococcus*, *Oenococcus* and *Lactobacillus*. Specific examples of suitable probiotic microorganisms are: *Saccharomyces cerevisiae*, *Bacillus coagulans*, *Bacillus licheniformis*, *Bacillus subtilis*, *Bifidobacterium bifidum*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Enterococcus faecium*, *Enterococcus faecalis*, *Lactobacillus acidophilus*, *Lactobacillus alimentarius*, *Lactobacillus casei* subsp. *casei*, *Lactobacillus casei Shirota*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii* subsp. *lactis*, *Lactobacillus farciminus*, *Lactobacillus gasseri*, *Lactobacillus helveticus*, *Lactobacillus johnsonii*, *Lactobacillus reuteri*, *Lactobacillus rhamnosus* (*Lactobacillus* GG), *Lactobacillus sake*, *Lactococcus lactis*, *Micrococcus varians*, *Pediococcus acidilactici*, *Pediococcus pentosaceus*, *Pediococcus acidilactici*, *Pediococcus halophilus*, *Streptococcus faecalis*, *Streptococcus thermophilus*, *Staphylococcus camosus*, and *Staphylococcus xylosus*. The probiotic microorganisms may be in powdered, dried form; especially in spore form for microorganisms which form spores. Further, if desired, the probiotic microorganism may be encapsulated to further increase the probability of survival; for example in a sugar matrix, fat matrix or polysaccharide matrix. Alternatively, the microorganism may be provided as a separately contained supplement to the main food composition.

In an embodiment of the invention, a combination of any of the above two or more pancreatic function promoters may be used.

Similarly, minerals used for promoting liver function are obtainable from natural or purified sources and combinations thereof. In preferred embodiments, the composition of the invention comprises a selected mineral in sufficient amount to exceed the minimum level set from time to time by the Association of American Feed Control Officials (AAFCO) by about 3 to 6 times (in other words about 300% to 500% of the AAFCO minimum).

Advantageously, the liver function promoter is present to be administered to the pet in an edible composition in an efficacious amount when administered according to a predetermined regimen, in order to obtain at least one of the benefits set out below. .

The intestinal mucosa function promoter of the invention may, in an embodiment, include a fat transportation aid agent or carrier, such as whey protein or a protease to help the formation of lipoproteins. An example of a suitable protease is papain. The diet or dietary composition may preferably comprise from about 0.1% to 1% by weight of papain on a DM basis. Should whey protein be included as a lipoprotein formation promoter, it is preferably present in concentrations from about 5% to 7% by weight of the diet on a DM basis.

The intestinal mucosa function promoter may, however, alternatively or in addition, include an anti-inflammatory agent. Suitable examples of these are the omega-3 fatty acids, lactoferrin, prebiotics, probiotic micro-organisms or fatty acids that have a profile specially selected to improve absorption. By way of example, a fatty acid group with a suitable absorption-enhancing profile is the medium chain triglycerides. In preferred embodiments, these are included in the diet at about 2% to 5% by weight of the diet on a DM basis.

Advantageously, the intestinal mucosa function promoter is present to be administered to the pet in an edible composition in an efficacious amount when administered according to a predetermined regimen in order to obtain at least one of the benefits set out below.

Where the intestinal mucosa function promoter comprises an omega 3 oil, it is preferably included in the diet from about 1% to 3% by weight on a DM basis. Where the diet or composition comprises lactoferrin, it is preferably included from about 100mg to 200mg per day. In the case of chicory, in preferred embodiments, it comprises from about 0.5% to 2% by weight of the diet or dietary composition on a dry matter basis. Prebiotics, for example inulin and/or oligosaccharides, should preferably make up from about 0.1% to 1% by weight

- Improved alertness, mental performance and cognitive ability, and
- Improved pet-owner interaction and bonding through increased activity and playfulness of the pet.

More general health benefits that are provided by the invention include

- Improved water turnover,
- Improved nutritional and overall health status,
- Improved antioxidant status by increasing vitamin (for example vitamin E) absorption,
- Improved nitrogen balance,
- Improved absorption of all lipid-soluble nutrients, for example fatty acids, vitamins A, D, E and K,
- Reduced renal overload by reduction of proteolysis, and
- Improved functions associated directly or indirectly with improved absorption of fat or antioxidants.

The invention thus also provides a method of reducing the effects of lipid malassimilation in a pet. The steps of this method may include administering to the pet a diet comprising an effective amount of an ingredient that maintains, promotes or enhances the capacity of the pet to digest lipid efficiently. The ingredient may be selected from those named above and belonging to the general categories of pancreatic function promoters, liver function-promoters and intestinal mucosa function-promoters.

By improving the capacity of a pet animal to absorb a lipid or lipid fraction that is a carrier of an essential nutrient, the capacity of the animal to absorb the essential nutrient is also improved. The essential nutrient is typically a vitamin such as vitamin A, E, D, or K. Preferred nutrients include vitamin E and arachadonic acid (ARA). Through enhanced absorption efficiency of these nutrients, for example vitamin E, the serum level thereof may be maintained and/or improved. Figure 1 illustrates the relationship that has been found to exist between fat digestibility, expressed as a percentage (%), and serum vitamin E (ug/ml).

The digestibility enhancing ingredient or agent may be used in a method of manufacturing a dietary composition or supplement or pharmaceutical composition for providing benefits associated with optimal lipid absorption in a pet animal, or for the prophylaxis of conditions associated with poor lipid absorption and low digestibility. Such methods are described further in the paragraphs that follow.

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To produce solid food pieces in gravy or gel, solid pieces of meat or other material, or both, may be mixed with a gravy. Solid pieces of other materials may also be used; such as rice grains, pasta or noodles, vegetable pieces, and the like.

The solid food pieces may be in the form of pieces of a thermally gelled matrix. The pieces of the thermally gelled matrix may be produced by any suitable procedure, for example the procedures described in any one of US patents 4,781,939, 5,132,137 and 5,567,466 and PCT application WO 97/02760.

The thermally gelled matrix may be formed in suitable equipment such as an emulsion mill or an extruder to form pieces or chunks. If an extruder is used, the emulsion may be forced through an orifice to provide the emulsion with a desired shape; for example of oval, square or rectangular cross-section. The extrudate may then be cooked in a suitable continuous cooking system; for example a tunnel oven using hot air, steam, mixtures of hot air and steam, or microwaves as the heating medium. The core temperature of the extrudate is raised such that the extrudate undergoes thermal gelling. For example, the core temperature may be raised to at least about 80°C; for example about 85°C to about 95°C. The gelled extrudate may then be cut into pieces and the pieces cooled to provide pieces of a thermally gelled matrix. The pieces may be subjected to flaking if desired. Cooling may be carried out by spraying water on the pieces. Alternatively, other cooling media may be used.

If a gravy is used with the solid food pieces, it may be produced from water, one or more starch or gums, and suitable flavoring agents. The gravy preferably comprises about 20% to about 80% by weight of the mixture of solid pieces and gravy. Suitable gums are kappa-carrageenan, locust bean gum, guar gum and xanthan gum.

If a gel is used with the solid food pieces, it may be produced from a suitable gelling agent, water and suitable flavoring agents. The gel preferably comprises about 20% to about 80% by weight of the mixture of solid pieces and gravy. Suitable gelling agents are proteins such as gelatin; gums such as alginates, kappa-carrageenan, locust bean gum, guar gum and xanthan gum, and the like. The gel or aspic may be prepared as is conventional.

Combinations of the processes described above may also be used. For example, a thermally gelled emulsion may be prepared as described above. Then solid food pieces,

the pet. However, an amount of the nutritional composition to provide a daily amount of about from 10g/kg to 25g/kg of body weight of the pet, on a dry matter basis, should be administered. Preferably, the amount should be in the range from about 12.5g/kg to 20g/kg of body weight on a DM basis in the diet.

Accordingly, the appropriate amount of the ingredient may then be included in the meal or treat, according to the pet's dietary requirements. The ingredient may be mixed in with the base formulation and then processed, or mixed into a gravy or other carrier for including with or adding to the food or treat.

It is believed that by providing a pet food composition as provided for above, making it available to minders or owners of elderly pets and drawing attention to the prospect that regular feeding of the composition to such pets can bring about at least a temporary alleviation of symptoms indicative of poor lipid assimilation in their pet, the pet minder will be encouraged to administer the pet the composition on a regular basis. A suitable way of drawing the attention of the minder to the benefits of the composition is by way of notice on the packaging of the food composition, alternatively by separate advertising thereof.

Numerous modifications may be made to the embodiments described above without departing from the scope of the invention. By way of example, and not limitation, trials of products of the invention will now be described for further illustration:

Example

A series of digestibility tests is used to scan which nutritional interventions among numerous possibilities may improve the fat digestibility of cats pre-selected for their low fat digestibility (i.e. below 80%) when added to a control cat food diet.

Lipid digestibility is assessed on a group of cats using materials and methods as follows:

- All participating cats are adults and in good health and are not pregnant.
- Each test diet is the only source of nourishment for the cats.
- Water is available to the cats at all times.
- Each cat's weight is recorded prior to the initiation of the test.
- Each cat is fed the amount of food required to cover its metabolizable energy requirements.
- The cats are fed the same control diet for a feces pre-collection period of 6 days.

improved in diet B. Cats are found to need a lower amount of diet B to cover their energy requirements than of diet A. Overall, cats appear to maintain their weight better when fed diet B than when fed diet A.

Example 2: Trial using a dry food diet.

This example uses a conventional dry cat food having a composition of about 31% protein, 15% fat, 4.5% fiber, 12% moisture and 5% ash, called diet C.

Another diet, called D, was based on a similar formulation but the following additional ingredients were included:

- A pancreatic function promoter: Lipases (0.15%).
- A Liver function promoter: Lecithin from Soya (1%)
- An Intestinal mucosa function promoter: Chicory (1%)

In this trial, a group of 20 cats with known low fat digestibility (i.e. less than 80%) is fed diets C and D, in a crossover design of two digestibility tests. Each diet is fed for a 15-day digestibility test, the first 5 days being an adaptation period and the remaining 10 days the fecal collection period. The cats on diet D are found to digest a higher percentage of lipid than those on diet C. Total energy digestibility and organic matter digestibility are also improved with diet D, when compared with diet C. Reduced fecal volume and odor were noted when cats were fed diet D instead of diet C.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

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- Increased longevity.

8. A method according to any one of the preceding claims wherein the composition is administered as a nutritionally balanced, ready-to-eat meal.

9. A method according to any one of the preceding claims wherein the composition is administered as a meal supplement.

10. A method according to claim 6 wherein the benefit is related to outward appearance and is observable in any one or more of:
    - Improved body condition;
    - Improved muscle tone;
    - Improved skin and coat condition; and
    - A younger look.

11. A nutrition management regimen for maintaining, improving, promoting or otherwise enhancing lipid digestibility comprises a dietary component for feeding regularly, according to predetermined directions, to a pet animal, the dietary component comprising a lipid assimilation-promoting ingredient.

12. A regimen according to claim 11 wherein the lipid assimilation-promoting ingredient is
    - A pancreatic function-promoter
    - A liver function-promoter,
    - An intestinal mucosa function-promoter or
    - A combination thereof.

13. A regimen according to claim 12 wherein the pancreatic function-promoter comprises a lipase, a gut pH modifier or a pancreatic extract.

14. A regimen according to claim 13 wherein the gut pH modifier includes one or more of an acidifier, an alkalanizer, a buffer, a prebiotic or a probiotic micro-organism.

25. A regimen according to claim 24 wherein the benefit that is related to gut function is observable in any one or more of:

- Increased nutrient and energy digestibility;
- Improved gut microflora, such as is observed in decreased small intestine bacterialovergrowth;
- Improved fecal consistency and/or odour;
- Optimized fecal volume;
- Improved regularity of food transit time;
- Reduced flatulence;
- Enhanced gut detoxification; and
- Improved absorption of fat-soluble nutrients.

26. A regimen according to claim 24 wherein the benefit that is related to outward appearance is observable in any one or more of:

- Improved body condition;
- Improved muscle tone;
- Improved skin and coat condition; and
- A younger look.

27. An edible composition for use in maintaining, improving, promoting or otherwise enhancing lipid digestibility in a pet animal comprising a lipid assimilation-promoting ingredient for administering regularly, according to predetermined directions, to a pet animal.

28. The composition of claim 27 wherein the ingredient is selected from the group consisting of pancreatic function-promoters, liver function-promoters, intestinal mucosa function-promoters and combinations thereof.

29. The composition of claim 27 or claim 28 wherein the ingredient is provided in a container for addition to a separately packaged complete meal or for administering apart from a meal.

30. A method of improving lipid absorption in a pet animal comprises administering to it an edible composition comprising at least one ingredient selected from the group consisting of lipase, pancreas extracts, taurine, vitamins, enzymes or lecithin.

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ABSTRACT

A method of providing a pet with a benefit relating to effective assimilation of a lipid is described wherein the pet is administered, as a part of, or in addition to its regular diet, an edible composition that contains an ingredient that maintains, promotes or enhances the capacity of the pet to digest lipid efficiently. The invention extends to compositions for use in promoting lipid assimilation in pets, particularly senior or elderly pets. The compositions include pancreatic, liver and intestinal mucosa function-promoters. In embodiments, the liver function-promoter may be selected from taurine, emulsifiers, vitamins, minerals, glutathione and glutathione promoters.